

**MICHIGAN DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH AND MEDICAL AFFAIRS**

**CERTIFICATE OF NEED REVIEW STANDARDS FOR
COMPUTED TOMOGRAPHY (CT) SCANNERS**

(By authority conferred on the Certificate of Need Commission by Sections 22215 and 22217 of Act No. 368 of the Public Acts of 1978, as amended, and Sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being Sections 333.22215, 333.22217, 24.207 and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for the approval and delivery of services for all projects approved and certificates of need issued under Part 222 of the Code which involve CT scanners.

(2) A CT scanner is covered medical equipment for purposes of Part 222 of the Code.

(3) The department shall use Sections 3, 4, 5, 6, 9, and 10, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(4) The department shall use Sections 7 and 8, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

Sec. 2. (1) For purposes of these standards:

(a) "Acquire a CT scanner" means obtaining possession or control of a CT scanner, whether fixed or mobile, by contract, ownership, or otherwise. For proposed projects involving mobile CT scanners this applies to the central service coordinator and/or host facility.

(b) "Billable procedure" means a CT procedure or set of procedures commonly billed as a single unit.

(c) "Body scans" include all spinal CT scans and any CT scan of an anatomical site below and including the neck.

(d) "Central service coordinator" means the organizational unit which has operational responsibility for a mobile CT scanner and which is a legal entity authorized to do business in the state of Michigan.

(e) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(f) "Computed tomography" or "CT" means the use of radiographic and computer techniques to produce cross-sectional images of the head or body.

(g) "CT equivalents" means the resulting number of units produced when the number of billable procedures for each category is multiplied by its respective conversion factor tabled in Section 9.

(h) "CT scanner" means x-ray CT scanning systems capable of performing either head or full body patient procedures. The term does not include emission-computed tomographic systems utilizing internally administered single-photon gamma ray emitters, positron annihilation CT systems, magnetic resonance, ultrasound computed tomographic systems, or similar technology.

(i) "CT scanner equipment," for purposes of sections 3 and 5 of these standards, means the equipment necessary to perform CT scans. It does not include any construction or renovations activities associated with the installation of the CT scanner, or service or maintenance contracts which under generally accepted accounting principles are properly chargeable as an expense of operation.

(j) "Driving time," for purposes of these standards, means the driving time in minutes as identified in the Michigan Department of Transportation Statewide Proximity Analysis.

(k) "Emergency room" means a designated area physically part of a licensed hospital and recognized by the department as having met the staffing and equipment requirements for the treatment of emergency

patients.

(l) "Head scans" include head or brain CT scans; including the maxillofacial area; the orbit, sella, or posterior fossa; or the outer, middle, or inner ear; or any other CT scan occurring above the neck.

(m) "Host facility" means the site at which a mobile CT scanner is located in order to provide CT scanner services.

(n) "Mobile CT scanner" means a CT scanner and transporting equipment operated by a central service coordinator and which must serve two or more host facilities.

(o) "Mobile CT scanner network" means the route (all host facilities) the mobile CT scanner is authorized to serve.

(p) "Replace/upgrade a CT scanner" means an equipment change proposed by an applicant which results in that applicant operating the same number of CT scanners before and after project completion.

(2) The definitions in Part 222 shall apply to these standards.

Section 3. Requirements for approval for applicants proposing to acquire their first CT scanner

Sec. 3. In order to be approved, an applicant proposing to acquire its first CT scanner shall demonstrate each of the following, as applicable:

(1) A hospital proposing to acquire its first fixed CT scanner, with a capital expenditure associated with the CT scanner equipment of greater than \$750,000, shall demonstrate each of the following:

(a) The hospital shall project an operating level of at least 3,500 CT equivalents for the second 12 month period after beginning operation of the CT scanner.

(b) The proposed site is a hospital licensed under Part 215 of the Code.

(c) The hospital operates an emergency room.

(d) The capital expenditure associated with the acquisition of the CT scanner equipment is greater than \$750,000.

(2) A hospital proposing to acquire its first fixed CT scanner, with a capital expenditure associated with the CT scanner equipment of \$750,000 or less, shall demonstrate each of the following:

(a) The hospital shall project an operating level of at least 1,500 CT equivalents for the second 12 month period after beginning operation of the CT scanner. If the proposed hospital site is more than 60 minutes driving time from another fixed CT scanner that is available on a 24 hour basis (either through on-site or on-call staffing arrangements), subsection (a) shall not apply.

(b) The proposed site is a hospital licensed under Part 215 of the Code.

(c) The hospital operates an emergency room.

(d) The capital expenditure associated with the acquisition of the CT scanner equipment is \$750,000 or less.

(3) An applicant, other than an applicant meeting all of the applicable requirements of subsection (1) or (2), proposing to acquire its first fixed CT scanner shall project an operating level of at least 7,500 CT equivalents per year for the second 12 month period after beginning operation of the CT scanner.

(4) An applicant proposing to acquire its first mobile CT scanner shall project an operating level of at least 3,500 CT equivalents per year for the second 12 month period after beginning operation of the CT scanner.

Section 4. Requirements for additional CT scanners - all applicants

Sec. 4. (1) If an application proposes an additional fixed CT scanner (second, third, etc.), in addition to a fixed CT scanner previously approved for that same person at the same site, in order to be approved, the applicant shall demonstrate each of the following:

(a) The applicant shall project an average operating level of at least 7,500 CT equivalents for each

fixed CT scanner, existing and proposed, operated by the applicant for the second 12 month period after initiation of operation of each additional CT scanner.

(b) All of the applicant's fixed CT scanners have performed an average of at least 10,000 CT equivalents per fixed CT scanner for the most recent continuous 12 month period preceding the applicant's request. In computing this average the department will divide the total number of CT equivalents performed by the applicant's total number of fixed CT scanners, including both operational and approved but not operational fixed CT scanners.

(2) If an application proposes an additional mobile CT scanner (second, third, etc.), in addition to a mobile CT scanner previously approved for that same person, in order to be approved, that person shall demonstrate each of the following:

(a) The applicant shall project an operating level of at least 4,000 CT equivalents for each existing and proposed mobile CT scanner for the second 12 month period after beginning operation of each additional CT scanner.

(b) All of the applicant's mobile CT scanners have performed an average of at least 5,500 CT equivalents per mobile CT scanner for the most recent continuous 12 month period preceding the applicant's request. In computing this average the department will divide the total number of CT equivalents performed by the applicant's total number of mobile CT scanners, including both operational and approved but not operational mobile CT scanners.

Section 5. Requirements for applications proposing to replace/upgrade a CT scanner

Sec. 5. In order to be approved, an applicant proposing to replace/upgrade an existing CT scanner shall demonstrate each of the following, as applicable:

(1) A hospital proposing to replace/upgrade an existing CT scanner which is the only fixed CT scanner operated at that site by the hospital, with a capital expenditure associated with the replacement CT scanner equipment of greater than \$750,000, shall demonstrate each of the following:

(a) The existing CT scanner to be replaced/upgraded performed at least 3,500 CT equivalents during the 12 month period immediately preceding the date of the application.

(b) The proposed site is a hospital licensed under Part 215 of the Code.

(c) The hospital operates an emergency room.

(d) The capital expenditure associated with the acquisition of the CT scanner equipment is greater than \$750,000.

(e) The replacement CT scanner will be located at the same site as the CT scanner to be replaced.

(2) A hospital proposing to replace/upgrade an existing CT scanner which is the only fixed CT scanner operated at that site by the hospital, with a capital expenditure associated with the replacement CT scanner equipment of \$750,000 or less, shall demonstrate each of the following:

(a) The existing CT scanner to be replaced/upgraded performed at least 1,500 CT equivalents during the 12 month period immediately preceding the date of the application. If the existing hospital site is more than 60 minutes driving time from another fixed CT scanner that is available on a 24 hour basis (either through on-site or on-call staffing arrangements), subsection (a) shall not apply.

(b) The proposed site is a hospital licensed under Part 215 of the Code.

(c) The hospital operates an emergency room.

(d) The capital expenditure associated with the acquisition of the replacement CT scanner equipment is \$750,000 or less.

(e) The replacement CT scanner will be located at the same site as the CT scanner being replaced.

(3) An applicant, other than an applicant meeting all of the applicable requirements of subsection (1) or (2), proposing to replace/upgrade an existing fixed CT scanner shall demonstrate that the volume of CT equivalents, during the 12 month period immediately preceding the date of the application, performed by the CT scanner to be replaced/upgraded was at least 7,500 CT equivalents if the applicant operates only

one fixed CT scanner, or an average of 7,500 CT equivalents for each fixed CT scanner if the applicant operates more than one fixed CT scanner at the same site.

(4) An applicant proposing to replace/upgrade an existing mobile CT scanner(s) shall demonstrate that the volume of CT equivalents, during the 12 month period immediately preceding the date of the application, performed by the CT scanner to be replaced/upgraded was at least 3,500 CT equivalents if the applicant operates only one mobile CT scanner or an average of 5,500 CT equivalents for each CT scanner if the applicant operates more than one mobile CT scanner for the same mobile CT scanner network.

(5) An applicant under this section shall demonstrate that the CT scanner(s) proposed to be replaced/upgraded is fully depreciated according to generally accepted accounting principles, or, that the existing equipment clearly poses a threat to the safety of the public, or, that the proposed replacement/upgraded CT scanner offers technological improvements which enhance quality of care, increase efficiency, and/or reduce operating costs and patient charges.

Section 6. Additional requirements for approval of mobile CT scanners

Sec. 6. (1) An applicant proposing to begin operation of a mobile CT scanner in Michigan shall demonstrate that it meets all of the following:

(a) A separate certificate of need application shall be submitted by the central service coordinator and each Michigan host facility.

(b) The normal route schedule, the procedures for handling emergency situations, and copies of all potential contracts related to the mobile CT scanner shall be included in the certificate of need application submitted by the central service coordinator.

(c) The requirements of Section 3, 4, or 5, as applicable, have been met.

(2) An applicant proposing to become a host facility on an existing mobile CT scanner network shall demonstrate that it meets all of the following:

(a) Approval of the application will not result in an increase in the number of operating mobile CT scanners for the mobile CT scanner network unless the requirements of Section 4 have been met.

(b) A separate certificate of need application has been filed for each host facility.

(3) An applicant proposing to replace a central service coordinator on an existing mobile CT scanner network shall demonstrate that approval of the application will not replace the CT scanner and transporting equipment unless the applicable requirements of Section 5 have been met.

Section 7. Project delivery requirements--terms of approval for all applicants

Sec. 7. (1) An applicant shall agree that, if approved, the services provided by the CT scanner(s) shall be delivered in compliance with the following terms of certificate of need approval:

(a) Compliance with these standards

(b) Compliance with applicable safety and operating standards

(c) Compliance with the following quality assurance standards:

(i) The approved CT scanners shall be operating at the applicable required volumes within the time periods specified in these standards, and annually thereafter.

(ii) The applicant shall establish a mechanism to assure that the CT scanner facility is staffed so that:

(1) The screening of requests for CT procedures and interpretation of CT procedures will be performed by physicians with training and experience in the appropriate diagnostic use and interpretation of cross-sectional images of the anatomical region(s) to be examined, and

(2) The CT scanner is operated by physicians and/or is operated by radiological technologists qualified by training and experience to operate the CT scanner safely and effectively.

For purposes of evaluating (ii)(1) the department shall consider it prima facie evidence of a satisfactory

assurance mechanism as to screening and interpretation if the applicant requires the screening of requests for and interpretations of CT procedures to be performed by physicians who are board certified or eligible in radiology or are neurologists or other specialists trained in cross-sectional imaging of a specific organ system. For purposes of evaluating (ii)(2) the department shall consider it prima facie evidence of a satisfactory assurance mechanism as to the operation of a CT scanner if the applicant requires the CT scanner to be operated by a physician or by a technologist registered by the American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT). However, the applicant may submit and the department may accept other evidence that the applicant has established a mechanism to assure that the CT scanner facility is appropriately and adequately staffed as to screening, interpretation, and/or operation of a CT scanner.

(iii) The applicant shall employ or contract with a radiation physicist to review the quality and safety of the operation of the CT scanner.

(iv) The applicant shall assure that at least one of the physicians responsible for the screening and interpretation as defined in subsection (ii)(1) will be in the CT facility or available on a 24-hour basis (either on-site or through telecommunication capabilities) to make the final interpretation.

(v) In the case of an urgent or emergency CT scan, the applicant shall assure that a physician so authorized by the applicant to interpret initial scans will be on-site within 1 hour following completion of the scanning procedure to render an initial interpretation of the scan. A final interpretation shall be rendered by a physician so authorized under subsection (ii)(1) within 24 hours.

(vi) The applicant shall have, within the CT scanner facility, equipment and supplies to handle clinical emergencies that might occur within the CT unit, with CT facility staff trained in CPR and other appropriate emergency interventions, and a physician on site in or immediately available to the CT scanner at all times when patients are undergoing scans.

(vii) Fixed CT scanner services at each facility shall be made available 24 hours a day for emergency patients.

(viii) The applicant shall accept referrals for CT scanner services from all appropriately licensed practitioners.

(ix) The applicant shall establish and maintain: (a) a standing medical staff and governing body (or its equivalent) requirement that provides for the medical and administrative control of the ordering and utilization of CT patient procedures, and (b) a formal program of utilization review and quality assurance. These responsibilities may be assigned to an existing body of the applicant, as appropriate.

(x) The applicant, to assure that the CT scanner will be utilized by all segments of the Michigan population, shall:

(a) not deny CT scanner services to any individual based on ability to pay or source of payment;
(b) provide CT scanning services to any individual based on the clinical indications of need for the service; and

(c) maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

Compliance with selective contracting requirements shall not be construed as a violation of this term.

(xi) The applicant shall participate in a data collection network established and administered by the department. The data may include, but is not limited to, annual budget and cost information, operating schedules, through-put schedules, demographic and diagnostic information, the volume of care provided to patients from all payor sources, and other data requested by the department, and approved by the commission. The applicant shall provide the required data on a separate basis for each separate and distinct site or unit as required by the department; in a format established by the department; and in a mutually agreed upon media. The department may elect to verify the data through on-site review of appropriate records.

(xii) Equipment to be replaced shall be removed from service.

(xiii) Within 10 days after beginning operation of a CT scanner, the applicant shall provide the department with a notice stating the first date on which the approved CT scanner began operating.

(2) The agreements and assurances required by this section shall be in the form of a certification authorized by the governing body of the applicant or its authorized agent.

(3) The operation of and referral of patients to the CT scanner shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

Section 8. Project delivery requirements - additional terms of approval for applicants involving mobile CT scanners

Sec. 8. (1) In addition to the provisions of Section 7, an applicant for a mobile CT scanner shall agree that the services provided by the mobile CT scanner(s) shall be delivered in compliance with the following terms of certificate of need approval:

(a) A host facility shall submit only one certificate of need application for a CT scanner for review at any given time.

(b) A mobile CT scanner with an approved certificate of need shall notify the Michigan Department of Public Health, Division of Construction, prior to dropping an existing host facility.

(c) A certificate of need shall be required to add a host facility.

(d) A certificate of need shall be required to change the central service coordinator.

(e) Each host facility must have at least one board certified or board eligible radiologist on its medical staff. The radiologist(s) shall be responsible for: (i) establishing patient examination and infusion protocol, and (ii) providing for the interpretation of scans performed by the mobile CT scanner.

(f) Each mobile CT scanner service must have an Operations Committee with members representing each host facility, the central service coordinator, and the central service medical director. This committee shall oversee the effective and efficient use of the CT scanner, establish the normal route schedule, identify the process by which changes are to be made to the schedule, develop procedures for handling emergency situations, and review the ongoing operations of the mobile CT scanner on at least a quarterly basis.

(g) The central service coordinator shall arrange for emergency repair services to be available 24 hours each day for the mobile CT scanner equipment as well as the vehicle transporting the equipment. In addition, to preserve image quality and minimize CT scanner downtime, calibration checks shall be performed on the CT scanner unit at least once each work day and routine maintenance services shall be provided on a regularly scheduled basis, at least once a week during hours not normally used for patient procedures.

(h) Each host facility must provide a properly prepared parking pad for the mobile CT scanner unit of sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for patients to enter the vehicle without going outside (such as a canopy or enclosed corridor). Each host facility must also provide the capability for processing the film and maintaining the confidentiality of patient records. A communication system must be provided between the mobile vehicle and each host facility to provide for immediate notification of emergency medical situations.

(i) A mobile CT scanner service shall operate under a contractual agreement that includes the provision of CT services at each host facility on a regularly scheduled basis.

(j) The volume of utilization at each host facility shall be reported to the department by the central service coordinator under the terms of Sec. 7.(1)(c)(xi).

(2) The agreements and assurances required by this section shall be in the form of a certification authorized by the owner or the governing body of the applicant or its authorized agent.

Section 9. Determination of CT Equivalents

Sec. 9. For purposes of these standards, CT equivalents shall be calculated as follows:

(a) Each billable procedure for the time period specified in the applicable section(s) of these standards shall be assigned to a category set forth in Table 1.

(b) The number of billable procedures for each category in the time period specified in the applicable section(s) of these standards shall be multiplied by the corresponding conversion factor in Table 1 to determine the number of CT equivalents for that category for that time period.

(c) The number of CT equivalents for each category shall be summed to determine the total CT equivalents for the time period specified in the applicable section(s) of these standards.

Table 1	Number of		Conversion		CT
Category	Billable CT		Factor		Equivalents
	Procedures				
Head Scans w/o Contrast	_____	X	1.00	=	_____
Head Scans with Contrast	_____	X	1.25	=	_____
Head Scans w/o & w Contrast	_____	X	1.75	=	_____
Body Scans w/o Contrast	_____	X	1.50	=	_____
Body Scans with Contrast	_____	X	1.75	=	_____
Body Scans w/o & w Contrast	_____	X	2.75	=	_____
TOTAL CT EQUIVALENTS	_____				_____

Section 10. Documentation of projections

Sec. 10. An applicant required to project volumes of service under Sections 3 and 4 shall specify how the volume projections were developed. This specification of projections shall include a description of the data source(s) used, assessments of the accuracy of these data, and the statistical method used to make the projections. Based on this documentation the department shall determine whether the projections are reasonable.

Section 11. Effect on prior certificate of need review standards; comparative reviews

Sec. 11. (1) These certificate of need review standards supersede and replace the Certificate of Need Review Standards for Computed Tomography Scanners approved by the Certificate of Need Commission and effective November 20, 1989.

(2) Projects reviewed under these standards shall not be subject to comparative review.